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§15.737-27 Decision of the General

On appeal from or review of the initial decision of the Administrative Law Judge, the General Counsel will make the agency decision. In making his/her decision, the General Counsel will review the record or such portions thereof as may be cited by the parties to permit limiting of the issues. A copy of the General Counsel's decision shall be transmitted to the respondent by the Director.

§15.737-28 Notice of disciplinary action.

(a) Upon the issuance of a final order suspending a former officer or employee from practice before the Department or a separate statutory agency thereof, the Director shall give notice thereof to appropriate officers and employees of the Department. Officers and employees of the Department shall refuse to participate in any appearance by such former officer or employee or to accept any communication which constitutes the prohibited practice before the Department or separate statutory agency thereof during the period of suspension.

(b) The Director shall take other appropriate disciplinary action as may be required by the final order.

Subpart D—Other Departmental Proceedings

§ 15.737-29 Review by the General Counsel.

In my proceeding before the Department, if an initial decision is made with respect to the disqualification of a representative or attorney for a party on the grounds of 18 U.S.C. 207(a), (b) or (c), such decision may be appealed to the General Counsel, who will make the agency decision on the issue.

PART 16—REGULATIONS IMPLE-MENTING THE PROGRAM FRAUD CIVIL REMEDIES ACT OF 1986

Sec.

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AUTHORITY: 31 U.S.C. 3801-3812.

Source: $52 \ FR \ 35071$, Sept. 17, 1987, unless otherwise noted.

§16.1 Basis and purpose.

- (a) Basis. This part implements the Program Fraud Civil Remedies Act of 1986, Pub. L. 99-509, sections 6101-6104, 100 Stat. 1874 (October 21, 1986), to be codified at 31 U.S.C. 3801-3812. 31 U.S.C. 3809 requires each authority head to promulgate regulations necessary to implement the provisions of the statute.
- (b) Purpose. This part

- (1) Establishes administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims or written statements to authorities or to their agents, and
- (2) Specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments.

§ 16.2 Definitions.

ALJ means an Administrative Law Judge in the authority appointed pursuant to 5 U.S.C. 3105 or detailed to the authority pursuant to 5 U.S.C. 3344.

Authority means the Department of the Treasury.

Authority head means the Assistant Secretary of the Treasury for Management.

Benefit, when used in the context of false statements made with respect to a benefit, means anything of value including but not limited to any advantage, preference, privilege, license, permit, favorable decision, ruling, status, or loan guarantee. This definition should be distinguished from the limitations on coverage of these regulations with respect to beneficiaries of specific benefit programs which are found in §16.3(c) of this part.

Claim means any request, demand, or submission—

- (a) Made to the authority for property, services, or money (including money representing grants, loans, insurance, or benefits):
- (b) Made to a recipient of property, services, or money from the authority or to a party to a contract with the authority—
- (1) For property or services if the United States—
- (i) Provided such property or services;
- (ii) Provided any portion of the funds for the purchase of such property or services; or
- (iii) Will reimburse such recipient or party for the purchase of such property or services; or
- (2) For the payment of money (including money representing grants, loans, insurance, or benefits) if the United States—

- (i) Provided any portion of the money requested or demanded; or
- (ii) Will reimburse such recipient or party for any portion of the money paid on such request or demand; or
- (c) Made to the authority which has the effect of decreasing an obligation to pay or account for property, services, or money, except that such term does not include any claim made in any return of tax imposed by the Internal Revenue Code of 1954.

Complaint means the administrative complaint served by the reviewing official on the defendant under §16.7 of this part.

Defendant means any person alleged in a complaint under §16.7 to be liable for a civil penalty or assessment under §16.3.

Department means the Department of the Treasury.

 ${\it Government}$ means the United States Government.

Individual means a natural person.

Initial decision means the written decision of the ALJ required by §16.10 or §16.37, and includes a revised initial decision issued following a remand or a motion for reconsideration.

Investigating official means the Inspector General of the Department of the Treasury.

Knows or has reason to know, means that a person, with respect to a claim or statement—

- (a) Has actual knowledge that the claim or statement is false, fictitious, or fraudulent:
- (b) Acts in deliberate ignorance of the truth or falsity of the claim or statement: or
- (c) Acts in reckless disregard of the truth or falsity of the claim or statement

Makes, wherever it appears, shall include the terms "presents," "submits," and "causes to be made, presented," or "submitted." As the context requires, making or made, shall likewise include the corresponding forms of such terms.

Person means any individual, partnership, corporation, association, private organization, State, political subdivision of a State, municipality, county, district, and Indian tribe, and includes the plural of that term.

Presiding officer means an administrative law judge appointed in the authority pursuant to 5 U.S.C. 3105 or detailed to the authority pursuant to section 3344 of such title.

Representative means an attorney designated in writing by a defendant to appear on his or her behalf in administrative hearings before the Department and to represent a defendant in all other legal matters regarding a complaint made pursuant to these regulations.

Reviewing official means the General Counsel, or another individual in the Legal Division of the Department designated by the General Counsel, who is—

- (a) Serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS-16; and
- (b) Is not subject to supervision by, or required to report to, the investigating official; and
- (c) Is not employed in the organization unit of the authority in which the investigating official is employed.

Statement means any representation, certification, affirmation, document, record, or accounting or bookkeeping entry made—

- (a) With respect to a claim or to obtain the approval or payment of a claim (including relating to eligibility to make a claim); or
- (b) With respect to (including relating to eligibility for)—
- (1) A contract with, or a bid or proposal for a contract with; or
- (2) A grant, loan, or benefit from, the authority, or any State, political subdivision of a State, or other party, if the United States Government provides any portion of the money or property under such contract or for such grant, loan, or benefit, or if the government will reimburse such State, political subdivision, or party of any portion of the money or property under such contract or for such grant, loan, or benefit, except that such term does not include any claim made in any return of tax imposed by the Internal Revenue Code of 1954.

§16.3 Basis for civil penalties and assessments.

- (a) Claims. (1) Except as provided in paragraph (c) of this section, any person who makes a claim that the person knows or has reason to know—
 - (i) Is false, fictitious, or fraudulent;
- (ii) Includes or is supported by any written statement which asserts a material fact which is false, fictitious, or fraudulent:
- (iii) Includes or is supported by any written statement that—
 - (A) Omits a material fact:
- (B) Is false, fictitious, or fraudulent as a result of such omission; and
- (C) Is a statement in which the person making such statement has a duty to include such material fact; or
- (iv) Is for payment for the provision of property or services which the person has not provided as claimed, shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than \$5,000 for each such claim.
- (2) Each voucher, invoice, claim form, or other individual request or demand for property, services, or money constitutes a separate claim.
- (3) A claim shall be considered made to an authority, recipient, or party when such claim is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of such authority, recipient, or party.
- (4) Each claim for property, services, or money is subject to a civil penalty under these regulations regardless of whether such property, services, or money is actually delivered or paid.
- (5) If the government has made any payment (including transferred property or provided services) on a claim, a person subject to a civil penalty under paragraph (a)(1) of this section shall also be subject to an assessment of not more than twice the amount of such claim or that portion thereof that is determined to be in violation of paragraph (a)(1) of this section. Such assessment shall be in lieu of damages sustained by the Government because of such claim.
- (b) Statements. (1) Except as provided in paragraph (c) of this section, any

person who makes a written statement that—

- (i) The person knows or has reason to know—
- (A) Asserts a material fact which is false, fictitious, or fraudulent; or
- (B) Is false, fictitious, or fraudulent because it omits a material fact that the person making the statement has a duty to include in such statement; and
- (ii) Includes or is accompanied by an express certification or affirmation of the truthfulness and accuracy of the content of the statement,
- shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than \$5,000 for each such statement.
- (2) Each written representation, certification, or affirmation constitutes a separate statement.
- (3) A statement shall be considered made to an authority when such statement is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of such authority.
- (c)(1) In the case of any claim or statement made by any individual relating to any of the benefits listed in paragraph (c)(2) of this section, received by such individual, such individual may be held liable for penalties and assessments under this section only if such claim or statement is made by such individual in making application for such benefits with respect to such individual's eligibility to receive such benefits.
- (2) For purposes of this paragraph, the term *benefits* means—
- (i) Benefits under the food stamp program (as defined in section 3(h) of the Food Stamp Act of 1977);
- (ii) Benefits under Chapters 11, 13, 15, 17, and 21 of Title 38;
- (iii) Benefits under the Black Lung Benefits Act:
- (iv) Any authority or other benefit under the Railroad Retirement Act of 1974;
- (v) Benefits under the National School Lunch Act;
- (vi) Benefits under any housing assistance program for lower income families or elderly or handicapped persons which is administered by the Sec-

retary of Housing and Urban Development or the Secretary of Agriculture;

- (vii) Benefits under the special supplemental food program for women, infants, and children established under section 17 of the Child Nutrition Act of 1966:
- (viii) Benefits under part A of the Energy Conservation in Existing Buildings Act of 1976;
- (ix) Benefits under the supplemental security income program under title XVI of the Social Security Act;
- (x) Old age, survivors, and disability insurance benefits under title II of the Social Security Act;
- (xi) Benefits under title XVIII of the Social Security Act;
- (xii) Aid to families with dependent children under a State plan approved under section 402(a) of the Social Security Act;
- (xiii) Medical assistance under a State plan approved under section 1902(a) of the Social Security Act;
- (xiv) Benefits under title XX of the Social Security Act;
- (xv) Benefits under section 336 of the Older Americans Act; or
- (xvi) Benefits under the Low-Income Home Energy Assistance Act of 1981, which are intended for the personal use of the individual who receives the benefits or for a member of the individual's family.
- (d) No proof of specific intent to defraud is required to establish liability under this section.
- (e) In any case in which it is determined that more than one person is liable for making a claim or statement under this section, each such person may be held liable for a civil penalty under this section.
- (f) In any case in which it is determined that more than one person is liable for making a claim under this section, and on which the Government has made payment (including transferred property or provided services), an assessment may be imposed against any such person or jointly and severally against any combination of such persons

§ 16.4 Investigation.

(a) If an investigating official concludes that a subpoena pursuant to the

authority conferred by 31 U.S.C. 3804(a) is warranted—

- (1) The subpoena so issued shall notify the person to whom it is addressed of the authority under which the subpoena is issued and shall identify the information, records, or documents sought;
- (2) The investigating official may designate a person to act on his behalf to receive the information, records, or documents sought; and
- (3) The person receiving such subpoena shall be required to tender to the investigating official or to the person designated to receive the information, records, or documents, a certification that the information, records, or documents sought have been produced, or that such information, records, or documents are not available and the reasons therefor, or that such information, records, or documents, suitably identified, have been withheld based upon the assertion of an identified legal privilege.
- (b) If the investigating official concludes that an action under the Program Fraud Civil Remedies Act may be warranted, the investigating official shall report the findings and conclusions of such investigation to the reviewing official.
- (c) Nothing in this section shall preclude or limit the investigating official's discretion to refer allegations directly to the Department of Justice for suit under the False Claims Act, 31 U.S.C. 3729-3731, or for other civil relief, or to preclude or limit such official's discretion to defer or postpone a report or referral to avoid interference with an investigation into criminal misconduct or a criminal prosecution.
- (d) Nothing in this section modifies any responsibility of the investigating official to report violations of criminal law to the Attorney General.

§ 16.5 Review by the reviewing official.

(a) If, based on the report of the investigating official under §16.4(b), the reviewing official determines that there is adequate evidence to believe that a person is liable under §16.3 of this part, the reviewing official shall transmit to the Attorney General a written notice of the reviewing offi-

cial's intention to issue a complaint under §16.7.

- (b) Such notice shall include—
- (1) A statement of the reviewing official's reasons for issuing a complaint;
- (2) A statement specifying the evidence that supports the allegations of liability:
- (3) A description of the claims or statements upon which the allegations of liability are based;
- (4) An estimate of the amount of money or the value, if any, of property, services, or other benefits requested or demanded in violation of §16.3 of this part; or, if no monetary value can be put on the property, service or benefit, a statement regarding the non-monetary consequences to the agency of a false statement.
- (5) A statement of any exculpatory or mitigating circumstances that may relate to the claims or statements known by the reviewing official or the investigating official; and
- (6) A statement that there is a reasonable prospect of collecting an appropriate amount of penalties and assessments. Such a statement may be based upon information then known or an absence of any information indicating that the person may be unable to pay such an amount.

§ 16.6 Prerequisites for issuing a complaint.

- (a) The reviewing official may issue a complaint under \$16.7 only if—
- (1) The Department of Justice approves the issuance of a complaint in a written statement described in 31 U.S.C. 3803(b)(l), and
- (2) In the case of allegations of liability under §16.3(a) with respect to a claim, the reviewing official determines that, with respect to such claim or a group of related claims submitted at the same time such claim is submitted (as defined in paragraph (b) of this section), the amount of money or the value of property or services demanded or requested in violation of §16.3(a) does not exceed \$150,000.
- (b) For the purposes of this section, a related group of claims submitted at the same time shall include only those claims arising from the same transaction (e.g., grant, loan, application, or

contract) that are submitted simultaneously as part of a single request, demand, or submission.

(c) Nothing in this section shall be construed to limit the reviewing official's authority to join in a single complaint against a person, claims that are unrelated or were not submitted simultaneously, regardless of the amount of money or the value of property or services demanded or requested, as long as the total amount for each claim does not exceed \$150,000.

§16.7 Complaint.

- (a) On or after the date the Attorney General or his designee approves the issuance of a complaint in accordance with 31 U.S.C. 3803(b)(1), the reviewing official may serve a complaint on the defendant, as provided in § 16.8.
 - (b) The complaint shall state-
- (1) The allegations of liability against the defendant, including the statutory basis for liability, an identification of the claims or statements that are the basis for the alleged liability, and the reasons why liability allegedly arises from such claims or statements;
- (2) The maximum amount of penalties and assessments for which the defendant may be held liable;
- (3) Instructions for filing an answer to request a hearing, including a specific statement of the defendant's right to request a hearing by filing an answer and to be represented by an attorney.
- (4) That the defendant has a right to review and obtain certain information pursuant to Section 16.20 herein; and
- (5) That failure to file an answer within 30 days of service of the complaint will result in the imposition of the maximum amount of penalties and assessments without right to appeal.
- (c) At the same time the reviewing official serves the complaint on the defendant(s), he or she shall serve the defendant with a copy of these regulations.

§16.8 Service of complaint.

(a) Service of a complaint must be made by a certified or registered mail or by delivery in any manner authorized by Rule 4(d) of the Federal Rules of Civil Procedure.

- (b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by—
- (1) Affidavit of the individual making service:
- (2) An acknowledged United States Postal Service return receipt card; or
- (3) Written acknowledgement of the defendant or his representative.

§16.9 Answer.

- (a) The defendant may request a hearing by filing an answer with the reviewing official within 30 days of service of the complaint. An answer shall be deemed to be a request for hearing.
 - (b) In the answer, the defendant—
- (1) Shall admit or deny each of the allegations of liability made in the complaint;
- (2) Shall state any defense on which the defendant intends to rely;
- (3) May state any reasons why the defendant contends that the penalties and assessments should be less than the statutory maximum; and
- (4) Shall state whether the defendant has authorized an attorney to act as defendant's representative, and shall state the name, address, and telephone number of the representative.

§ 16.10 Default upon failure to file an answer.

- (a) If the defendant does not file an answer within the time prescribed in §16.9(a), the reviewing official may refer the complaint to the ALJ for initial decision.
- (b) Upon the referral of the complaint, the ALJ shall promptly serve on defendant in the manner prescribed in §16.8, a notice that an initial decision will be issued under this section.
- (c) If the defendant fails to file a timely answer, the ALJ shall assume the facts alleged in the complaint to be true and, if such facts eatablish liability under §16.3, the ALJ shall issue an initial decision imposing the maximum amount of penalties and assessments allowed under the statute.
- (d) Except as otherwise provided in this section, by failing to file a timely answer, the defendant waives any right to further review of the penalties and assessments imposed under paragraph

(c) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

- (e) If, before such an initial decision becomes final, the defendant files a motion with the ALJ, and serves a copy on the agency, seeking to reopen on the grounds that extraordinary circumstances prevented the defendant from filing a timely answer, the initial decision shall be stayed pending the ALJ's decision on the motion. The ALJ shall permit the agency a reasonable amount of time, not less than 15 calendar days, to respond to the defendant's motion.
- (f) If, on such motion, the defendant can demonstrate extraordinary circumstances excusing the failure to file a timely answer, the ALJ shall withdraw the initial decision, if such a decision has been issued pursuant to paragraph (c) of this section, and shall grant the defendant an opportunity to answer the complaint.

(g) A decision of the ALJ denying a defendant's motion under paragraph (e) of this section is not subject to reconsideration under §16.38.

- (h) The defendant may appeal to the authority head the decision denying a motion to reopen by filing a notice of appeal with the authority head within 15 days after the ALJ denies the motion. The timely filing of a notice of appeal shall stay the initial decision until the authority head decides the issue.
- (i) If the defendant files a timely notice of appeal with the authority head, the ALJ shall forward the record of the proceeding to the authority head.
- (j) The authority head shall decide expeditiously, and based solely on the record before the ALJ, whether extraordinary circumstances excuse the defendant's failure to file a timely answer.
- (k) If the authority head decides that extraordinary circumstances excuse the defendant's failure to file a timely answer, the authority head shall remand the case to the ALJ with instructions to grant the defendant an opportunity to file an answer.
- (l) If the authority head decides that the defendant's failure to file a timely answer is not excused, the authority

head shall reinstate the initial decision of the ALJ, which shall become final and binding upon the parties 30 days after the authority head issues such decision.

§16.11 Referral of complaint and answer to the ALJ.

Upon receipt of an answer, the reviewing official shall file the complaint and answer with the ALJ.

§ 16.12 Notice of hearing.

- (a) When the ALJ receives the complaint and answer, the ALJ shall promptly serve a notice of hearing upon the defendant and the agency representative in the manner prescribed by §16.8.
- (b) Such notice shall include—
- (1) The tentative time and place, and the nature of the hearing;
- (2) The legal authority and jurisdiction under which the hearing is to be held:
- (3) The matters of fact and law to be asserted:
- (4) A description of the procedures for the conduct of the hearing;
- (5) The names, addresses, and telephone numbers of the representatives of the Government and of the defendant, if any; and
- (6) Such other matters as the ALJ deems appropriate.

§16.13 Parties to the hearing.

- (a) The parties to the hearing shall be the defendant and the authority.
- (b) Pursuant to 31 U.S.C. 3730(c)(5), a private plaintiff under the False Claims Act may participate in these proceedings to the extent authorized by the provisions of that Act.

§ 16.14 Separation of functions.

- (a) The investigating official, the reviewing official, and any employee or agent of the authority who takes part in investigating, preparing, or presenting a particular case may not, in such case or a factually related case—
- (1) Participate in the hearing as the ALJ;
- (2) Participate or advise in the initial decision or the review of the initial decision by the authority head, except as a witness or a representative in public proceedings; or

- (3) Make the collection of penalties and assessments under 31 U.S.C. 3806.
- (b) The ALJ shall not be responsible to, or subject to the supervision or direction of the investigating official or the reviewing official.
- (c) Except as provided in paragraph (a) of this section, the representative for the Government may be an attorney employed anywhere in the Legal Division of the Department, or an attorney employed in the offices of either the investigating official or the reviewing official; however the representative of the Government may not participate or advise in the review of the initial decision by the authority head.

§16.15 Ex parte contacts.

No party or person (except employees of the ALJ's office) shall communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 16.16 Disqualification of reviewing official or ALJ.

- (a) A reviewing official or ALJ in a particular case may disqualify himself or herself at any time.
- (b) A party may file with the ALJ a motion for disqualification of a reviewing official or an ALJ. Such motion shall be accompanied by an affidavit alleging personal bias or other reason for disqualification.
- (c) Such motion and affidavit shall be filed promptly upon the party's discovery of reasons requiring disqualification, or such objections shall be deemed waived.
- (d) Such affidavit shall state specific facts that support the party's assertion that personal bias or other reason for disqualification exists and the time and circumstances of the party's discovery of such facts. It shall be accompanied by a certificate of the representative of record that it is made in good faith.
- (e) Upon the filing of such a motion and affidavit, the ALJ shall proceed no further in the case until he or she resolves the matter of disqualification in

- accordance with paragrpah (f) of this section.
- (f)(1) If the ALJ determines that a reviewing official is disqualified, the ALJ shall dismiss the complaint without prejudice.
- (2) If the ALJ disqualifies himself or herself, the agency shall seek to have the case promptly reassigned to another ALJ.
- (3) If the ALJ denies a motion to disqualify, the authority head may determine the matter only as part of his or her review of the initial decision upon appeal, if any.

§16.17 Rights of parties.

Except as otherwise limited by this part, all parties may—

- (a) Be accompanied, represented, and advised by an attorney;
- (b) Participate in any conference held by the ALJ;
 - (c) Conduct discovery;
- (d) Agree to stipulations of fact or law, which shall be made part of the record:
- (e) Present evidence relevant to the issues at the hearing;
- (f) Present and cross-examine witnesses:
- (g) Present oral arguments at the hearing as permitted by the ALJ; and
- (h) Submit written beliefs and proposed findings of fact and conclusions of law after the hearing.

§16.18 Authority of the ALJ.

- (a) The ALJ shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.
 - (b) The ALJ has the authority to—
- (1) Set and change the date, time, and place of the hearing upon reasonable notice to the parties;
- (2) Continue or recess the hearing in whole or in part for a reasonable period of time:
- (3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;
- (4) Administer oaths and affirmations:
- (5) Issue subpoenas requiring the attendance of witnesses and the production of documents at depositions or at hearings;

- (6) Rule on motions and other procedural matters;
- (7) Regulate the scope and timing of discovery;
- (8) Regulate the course of the hearing and the conduct of representatives and parties;
 - (9) Examine witnesses;
- (10) Receive, rule on, exclude, or limit evidence:
- (11) Upon motion of a party, take official notice of facts;
- (12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;
- (13) Conduct any conference, argument, or hearing on motions in person or by telephone; and
- (14) Exercise such other authority as is necessary to carry out the responsibilities of the ALJ under this part.
- (c) The ALJ does not have the authority to make any determinations regarding the validity of Federal statutes or regulations, or Departmental orders, Directives, or other published rules

§ 16.19 Prehearing conferences.

- (a) The ALJ may schedule prehearing conferences as appropriate.
- (b) Upon the motion of any party, the ALJ shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.
- (c) The ALJ may use prehearing conferences to discuss the following:
 - (1) Simplification of the issues;
- (2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement:
- (3) Stipulations, admissions of fact or the content and authenticity of documents:
- (4) Whether the parties can agree to submission of the case on a stipulated record:
- (5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;
- (6) Limitation of the number of witnesses:
- (7) Scheduling dates for the exchange of witness lists and of proposed exhibits:

- (8) Discovery;
- (9) The time and place for the hearing; and
- (10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.
- (d) The ALJ may issue an order containing all matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 16.20 Disclosure of documents.

- (a) Upon written request to the reviewing official, the defendant may review any relevant and material documents, transcripts, records, and other material that relate to the allegations set out in the complaint and upon which the findings and conclusions of the investigating official under §16.4(b) are based unless such documents are subject to a privilege under Federal law. The Department shall schedule such review at a time and place convenient to it. Upon payment of fees for duplication, the defendant may obtain copies of such documents.
- (b) Upon written request to the reviewing official, the defendant also may obtian a copy of all exculpatory information in the possession of the reviewing official or investigating official relating to the allegations in the complaint, even if it is contained in a document that would otherwise be privileged. If the document would otherwise be privileged, only that portion containing exculpatory information must be disclosed.
- (c) The notice sent to the Attorney General from the reviewing official as described in §16.5 is not discoverable under any circumstances.
- (d) The defendant may file a motion to compel disclosure of the documents subject to the provisions of this section. Such a motion may only be filed with the ALJ following the filing of an answer pursuant to §16.9.

§16.21 Discovery.

- (a) The following types of discovery are authorized:
- (1) Requests for production of documents for inspection and copying;
- (2) Requests for admissions of the authenticity of any relevant document or of the truth of any relevant fact;
- (3) Written interrogatories; and

- (4) Depositions.
- (b) For the purposes of this section and §§16.22 and 16.23, the term "documents" includes information, documents, reports, answers, records, accounts, papers, and other data, either paper or electronic, and other documentary evidence. Nothing contained herein shall be interpreted to require the creation of a document.
- (c) Unless mutually agreed to by the parties, discovery is available only as ordered by the ALJ. The ALJ shall regulate the timing of discovery.
- (d) Motions for discovery. (1) A party seeking discovery may file a motion with the ALJ if it is not made available by another party on an informal basis. Such a motion shall be accompanied by a copy of the requested discovery, or in the case of depositions, a summary of the scope of the proposed deposition, and a description of the efforts which have been made by the party to obtain discovery.
- (2) Within ten days of service, a party may file an opposition to the motion and/or a motion for protective order as provided in §16.24.
- (3) The ALJ may grant a motion for discovery only if he or she finds that the discovery sought—
- (i) Is necessary for the expeditious, fair, and reasonable consideration of the issues;
- (ii) Is not unduly costly or burdensome:
- (iii) Will not unduly delay the proceeding; and
- (iv) Does not seek privileged information.
- (4) The burden of showing that discovery should be allowed is on the party seeking discovery.
- (5) The ALJ may grant discovery subject to a protective order under §16.24.
- (e) *Depositions.* (1) If a motion for deposition is granted, the ALJ shall issue a subpoena for the deponent, which may require the deponent to produce documents. The subpoena shall specify the time and place at which the deposition will be held.
- (2) The party seeking to depose shall serve the subpoena in the manner prescribed in §16.8.
- (3) The deponent may file with the ALJ a motion to quash the subpoena or

- a motion for a protective order within ten days of service.
- (4) The party seeking to depose shall provide for the taking of a verbatim transcript of the deposition, which it shall make available to all other parties for inspection and copying.
- (f) Each party shall bear its own costs of discovery.

§ 16.22 Exchange of witness lists, statements, and exhibits.

- (a) At least 15 days before the hearing or at such other time as may be ordered by the ALJ, the parties shall exchange witness lists, copies of prior statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with §16.33(b). At the time the above documents are exchanged, any party that intends to rely on the transcript of deposition testimony in lieu of live testimony at the hearing, if permitted by the ALJ, shall provide each party with a copy of the specific pages of the transcript it intends to introduce into evidence.
- (b) If a party objects, the ALJ shall not admit into evidence the testimony of any witness whose name does not appear on the witness list or any exhibit not provided to the opposing party as provided above unless the ALJ finds good cause and that there is no prejudice to the objecting party.
- (c) Unless another party objects within the time set by the ALJ, documents exchanged in accordance with paragraph (a) of this section, shall be deemed to be authentic for the purpose of admissibility at the hearing.

§ 16.23 Subpoenas for attendance at hearing.

- (a) A party wishing to procure the appearance and testimony of any individual at the hearing may request that the ALJ issue a subpoena.
- (b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.
- (c) A party seeking a subpoena shall file a written request therefor not less than 15 days before the date fixed for the hearing unless otherwise allowed

by the ALJ for good cause shown. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

- (d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to bring with him or her.
- (e) The party seeking the subpoena shall serve it in the manner prescribed in §16.8. A subpoena on a party or upon an individual under the control of a party may be served by first class mail.
- (f) A party or the individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within ten days after service or on or before the time specified in the subpoena for compliance if it is less than ten days after service.

§16.24 Protective order.

- (a) A party or a prospective witness or deponent may file a motion for a protective order with respect to discovery sought by an opposing party or with respect to the hearing, seeking to limit the availability or disclosure of evidence.
- (b) In issuing a protective order, the ALJ may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:
 - (1) That the discovery not be had;
- (2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;
- (3) That the discovery may be had only through a method of discovery other than that requested;
- (4) That certain matters not be inquired into, or that the scope of discovery be limited to certain matters;
- (5) That discovery be conducted with no one present except persons designated by the ALJ;
- (6) That the contents of discovery or evidence be sealed;
- (7) That a deposition after being sealed be opened only by order of the ALJ;
- (8) That a trade secret or other confidential research, development, com-

mercial information, or facts pertaining to any criminal investigation, proceeding, or other administrative investigation not be disclosed or be disclosed only in a designated way; or

(9) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the ALJ.

§ 16.25 Fees.

The party requesting a subpoena shall pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage shall accompany the subpoena when served, except that when a subpoena is issued on behalf of the authority, a check for witness fees and mileage need not accompany the subpoena.

§ 16.26 Form, filing and service of papers.

- (a) Form. (1) Documents filed with the ALJ shall include a original and two copies.
- (2) Every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the ALJ, and a designation of the paper (e.g., motion to quash subpoena).
- (3) Every pleading and paper shall be signed by, and shall contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.
- (4) Papers are considered filed when they are mailed. Date of mailing may be etablished by a certificate from the party or its representative or by proof that the document was sent by certified or registered mail.
- (b) Service. A party filing a document with the ALJ shall, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document other than the complaint or notice of hearing shall be made by delivering or mailing a copy to the party's last known address. When a party is represented by an attorney, service shall be made upon such representative in lieu of the actual party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, shall be proof of service.

§16.27 Computation of time.

- (a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which event it includes the next business day.
- (b) When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal Government shall be excluded from the computation. When the period of time allowed is more than seven days, all intervening calendar days are included in the computation.
- (c) Where a document has been served or issued by mail, an additional five days will be added to the time permitted for any response.

§ 16.28 Motions.

- (a) Any application to the ALJ for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the ALJ and served on all other parties.
- (b) Except for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The ALJ may require that oral motions be reduced to writing.
- (c) Within 15 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to such motion.
- (d) The ALJ may not grant a written motion before the time for filing responses thereto has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.
- (e) The ALJ shall make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§16.29 Sanctions.

- (a) The ALJ may sanction a person, including any party or representative for— $\,$
- (1) Failing to comply with an order, rule, or procedure governing the proceeding;
- (2) Failing to prosecute or defend an action; or
- (3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.
- (b) Any such sanction, including but not limited to those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the nature of the failure or misconduct.
- (c) When a party fails to comply with an order, including an order for taking a deposition, the production of evidence within the party's control, or a request for admission, the ALJ may—
- (1) Draw an inference in favor of the requesting party with regard to the information sought;
- (2) In the case of requests for admission, deem each matter of which an admission is requested to be admitted:
- (3) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon testimony relating to the information sought; and
- (4) Strike any part of the pleadings or other submissions of the party failing to comply with such request.
- (d) If a party fails to prosecute or defend an action under this part commenced by service of a notice of hearing, the ALJ may dismiss the action or may issue an initial decision imposing penalties and assessments.
- (e) The ALJ may refuse to consider any motion, request, response, brief or other document which is not filed in a timely fashion.

§16.30 The hearing and burden of proof.

- (a) The ALJ shall conduct a hearing on the record in order to determine whether the defendant is liable for a civil penalty or assessment under §16.3 and, if so, the appropriate amount of any such civil penalty or assessment considering any aggravating or mitigating factors.
- (b) The authority shall have the burden of proving defendant's liability and

any aggravating factors by a preponderance of the evidence.

- (c) The defendant shall have the burden of proving any affirmative defenses and any mitigating factors by a preponderance of the evidence.
- (d) The hearing shall be open to the public unless otherwise ordered by the ALJ for good cause shown.

§16.31 Determining the amount of penalties and assessments.

- (a) In determining an appropriate amount of civil penalties and assessements, the ALJ and upon appeal, the authority head, should evaluate any circumstances that mitigate or aggravate the violation and should articulate in their opinions the reasons that support the penalties and assessments they impose. Because of the intangible costs of fraud, the expense of investigating such conduct, and the need to deter others who might be similarly tempted, double damages and a significant civil penalty ordinarily should be imposed.
- (b) Although not exhaustive, the following factors are among those that may influence the ALJ and the authority head in determining the amount of penalties and assessments to impose with respect to the misconduct (i.e., the false, fictitious, or fraudulent claims or statements) charged in the complaint:
- (1) The number of false, fictitious, or fraudulent claims or statements;
- (2) The time period over which such claims or statements were made;
- (3) The degree of the defendant's culpability with respect to the misconduct:
- (4) The amount of money or the value of the property, services, or benefit falsely claimed;
- (5) The value of the Government's actual loss as a result of the misconduct, including foreseeable consequential damages and the costs of investigation;
- (6) The relationship of the amount imposed as civil penalties to the amount of the Government's loss;
- (7) The potential or actual impact of the misconduct upon national defense, public health or safety, or public confidence in the management of Government programs and operations;

- (8) Whether the defendant has engaged in a pattern of the same or similar misconduct;
- (9) Whether the defendant attempted to conceal the misconduct;
- (10) The degree to which the defendant has involved others in the misconduct or in concealing it;
- (11) Where the misconduct of employees or agents is imputed to the defendant, the extent to which the defendant's practices fostered or attempted to preclude such misconduct;
- (12) Whether the defendant cooperated in or obstructed an investigation of the misconduct;
- (13) Whether the defendant assisted in identifying and prosecuting other wrongdoers;
- (14) The complexity of the program or transaction, and the degree of the defendant's sophistication with respect to it, including the extent of the defendant's prior participation in the program or in similar transactions;
- (15) Whether the defendant has been found, in any criminal, civil, or administrative proceeding to have engaged in similar misconduct or to have dealt dishonestly with the Government of the United States or of a State, directly or indirectly; and
- (16) The need to deter the defendant and others from engaging in the same or similar misconduct.
- (c) Nothing in this section shall be construed to limit the ALJ or the authority head from considering any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

§ 16.32 Location of hearing.

- (a) The hearing may be held—
- (1) In any judicial district of the United States in which the defendant resides or transacts business;
- (2) In any judicial district of the United States in which the claim or statement in issue was made; or
- (3) In such other place as may be agreed upon by the defendant and the ALJ.
- (b) Each party shall have the opportunity to present argument with respect to the location of the hearing.

(c) The hearing shall be held at the place and at the time ordered by the ALJ.

§ 16.33 Witnesses.

- (a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.
- (b) At the discretion of the ALJ, testimony may be admitted in the form of a written statement or deposition. Any such written statement must be provided to all other parties along with the last known address of such witness, in a manner which allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing and deposition transcripts shall be exchanged as provided in §16.22(a).
- (c) The ALJ shall exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to—
- (1) Make the interrogation and presentation effective for the ascertainment of the truth,
- (2) Avoid needless consumption of time, and
- (3) Protect witnesses from harassment or undue embarrassment.
- (d) The ALJ shall permit the parties to conduct such cross examination as may be required for a full and true disclosure of the facts.
- (e) At the discretion of the ALJ, a witness may be cross-examined on matters relevant to the proceeding without regard to the scope of his or her direct examination. To the extent permited by the ALJ, cross-examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse party, or a witness identified with an adverse party.
- (f) Upon motion of any party, the ALJ shall order witnesses excluded so that they cannot hear the testimony of other witnesses. This rule does not authorize exclusion of—
 - (1) A party who is an individual;
- (2) In the case of a party that is not an individual, an officer or employee of

the party designated by the party's representative; or

(3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual employed by the Government engaged in assisting the representative for the Government.

§16.34 Evidence.

- (a) The ALJ shall determine the admissibility of evidence.
- (b) Except as provided herein, the ALJ shall not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, *e.g.*, to exclude unreliable evidence.
- (c) The ALJ shall exclude irrelevant, immaterial, or incompetent evidence.
- (d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.
- (e) Although relevant, evidence may be excluded if it is privileged under Federal law.
- (f) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.
- (g) The ALJ shall permit the parties to introduce rebuttal witnesses and evidence.
- (h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the ALJ pursuant to §16.24.

§ 16.35 The record.

- (a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ at a cost not to exceed the actual cost of duplication.
- (b) The transcript of testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the authority head.
- (c) The record may be inspected and copied (upon payment of a reasonable fee) by anyone, unless otherwise ordered by the ALJ pursuant to §16.24.

§16.36 Post-hearing briefs.

The ALJ may require the parties to file post-hearing briefs. The ALJ shall fix the time for filing such briefs, not to exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§16.37 Initial decision.

- (a) The ALJ shall issue an initial decision, based solely on the record, which shall contain findings of fact, conclusion of law, and the amount of any penalties and assessments imposed.
- (b) The findings of fact shall include a finding on each of the following issues:
- (1) Whether the claims or statements identified in the complaint, or any portions thereof, violate §16.3;
- (2) If the person is liable for penalties of assessments, the appropriate amount of any such penalties or assessments considering any mitigating or aggravating factors that he or she finds in the case, such as those described in §16.31.
- (c) The ALJ shall promptly serve the initial decision on all parties within 90 days after the time for submission of post-hearing briefs and reply briefs (if permitted) has expired. The ALJ shall at the same time serve all defendants with a statement describing the right of any defendant determined to be liable for a civil penalty or assessment to file a motion for reconsideration with the ALJ or a notice of appeal with the authority head. If the ALJ fails to meet the deadline contained in this paragraph, he or she shall notify the parties of the reason for the delay and shall set a new deadline.
- (d) Unless the initial decision of the ALJ is timely appealed to the authority head, or a motion for reconsideration of the initial decision is timely filed, the initial decision shall constitute the final decision of the authority head and shall be final and binding on the parties 30 days after it is issued by the ALJ.

§ 16.38 Reconsideration of initial decision.

- (a) Except as provided in paragraph (d) of this section, any party may file a motion for reconsideration of the initial decision within 20 days of receipt of the initial decision. If service was made by mail, receipt will be presumed to be five days from the date of mailing in the absence of contrary proof.
- (b) Every such motion must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Such motion shall be accompanied by a supporting brief.
- (c) Responses to such motions shall be allowed only upon request of the ALJ.
- (d) No party may file a motion for reconsideration of an initial decision that has been revised in response to a previous motion for reconsideration.
- (e) The ALJ may dispose of a motion for reconsideration by denying it or by issuing a revised initial decision.
- (f) When a motion for reconsideration is made, the time periods for appeal to the authority head contained in §16.38, and for finality of the initial decision in §16.36(d), shall begin on the date the ALJ issues the denial of the motion for reconsideration or a revised initial decision, as appropriate.

§ 16.39 Appeal to authority head.

- (a) Any defendant who has filed a timely answer and who is determined in an initial decision to be liable for a civil penalty or assessment may appeal such decision to the authority head by filing a notice of appeal with the authority head in accordance with this section.
- (b)(1) No notice of appeal may be filed until the time period for filing a motion for reconsideration under §16.38 has expired.
- (2) If a motion for reconsideration is timely filed, a notice of appeal must be filed within 30 days after the ALJ denies the motion or issues a revised initial decision, whichever applies.
- (3) If no motion for reconsideration is timely filed, a notice of appeal must be filed within 30 days after the ALJ issues the initial decision.
- (4) The authority head may extend the initial 30 days period for an additional 30 days if the defendant files

with the authority head a request for extension within the initial 30 days period and shows good cause.

- (c) If the defendant files a timely notice of appeal with the authority head, the ALJ shall forward the notice of appeal and record of the proceeding to the authority head.
- (d) A notice of appeal shall be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions.
- (e) The representative for the agency may file a brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief.
- (f) There is no right to appear personally before the authority head.
- (g) There is right to appeal any interlocutory ruling by the ALJ.
- (h) In reviewing the initial decision, the authority head shall not consider any objection that was not raised before the ALJ unless a demonstration is made of extraordinary circumstances causing the failure to raise the objection.
- (i) If any party demonstrates to the satisfaction of the authority head, prior to the issuance of the authority head's decision that additional evidence not presented at such hearing is material and that there were reasonable grounds for the failure to present such evidence at the hearing, the authority head shall remand the matter to the ALJ for consideration of such additional evidence.
- (j) The authority head may affirm, reduce, reverse, compromise, remand, or settle any penalty or assessment, determined by the ALJ in any initial decision.
- (k) The authority head shall promptly serve each party to the appeal to the ALJ with a copy of the decision of the authority head. At the same time the authority head shall serve the defendant with a statement describing the defendant's right to seek judicial review.
- (l) Unless a petition for judicial review is filed as provided in 31 U.S.C. 3805 after a defendant has exhausted all administrative remedies under this part and within 60 days after the date on which the authority head serves the defendant with a copy of the authority head's decision, a determination that a

defendant is liable under §16.3 is final and is not subject to judicial review.

\$16.40 Stays ordered by the Department of Justice.

If at any time the Attorney General or an Assistant Attorney General designated by the Attorney General transmits to the authority head a written finding that continuation of the administrative process described in this part with respect to a claim or statement may adversely affect any pending or potential criminal or civil action related to such claim or statement, the authority head shall stay the process immediately. In such a case, the authority head may order the process resumed only upon receipt of the written authorization of the Attorney General.

§16.41 Stay pending appeal.

- (a) An initial decision is stayed automatically pending disposition of a motion for reconsideration or of an appeal to the authority head.
- (b) No administrative stay is available following a final decision of the authority head.

§16.42 Judicial review.

Section 3805 of title 31, United States Code, authorizes judicial review by an appropriate United States District Court of a final decision of the authority head imposing penalties or assessments under this part and specifies the procedures for such review.

§ 16.43 Collection of civil penalties and

Sections 3806 and 3808(b) of title 31, United States Code, authorize actions for collection of civil penalties and assessments imposed under this part and specify the procedures for such actions.

§16.44 Right to administrative offset.

The amount of any penalty or assessment which has become final, or for which a judgment has been entered under §16.42 or §16.43, or any amount agreed upon in a compromise or settlement under §16.46, may be collected by administrative offset under 31 U.S.C. 3716, except that an administrative offset may not be made under this subsection against a refund of an overpayment of Federal taxes, then or later

owing by the United States to the defendant.

§16.45 Deposit in Treasury of United States.

All amounts collected pursuant to this part shall be deposited as miscellaneous receipts in the Treasury of the United States, except as provided in 31 U.S.C. 3806(g).

§ 16.46 Compromise or settlement.

- (a) Parties may make offers of compromise or settlement at any time.
- (b) The reviewing official has the exclusive authority to compromise or settle a case under this part at any time after the date on which the reviewing official is permitted to issue a complaint and before the date on which the ALJ issues an initial decision.
- (c) The authority head has exclusive authority to compromise or settle a case under this part at any time after the date on which the ALJ issues an initial decision, except during the pendency of any review under §16.42 or during the pendency of any action to collect penalties and assessments under §16.43.
- (d) The Attorney General has exclusive authority to compromise or settle a case under this part during the pendency of any review under §16.42 or of any action to recover penalties and assessments under 31 U.S.C. 3806.
- (e) The investigating official may recommend settlement terms to the reviewing official, the authority head, or the Attorney General, as appropriate. The reviewing official may recommend settlement terms to the authority head, or the Attorney General, as appropriate.
- (f) Any compromise or settlement must be in writing and signed by all parties and their representatives.

§ 16.47 Limitations.

- (a) The notice of hearing with respect to a claim or statement must be served in the manner specified in §16.8 within 6 years after the date on which such claim or statement is made.
- (b) If the defendant fails to file a timely answer, service of a notice under §16.10(b) shall be deemed a notice of hearing for purposes of this section.

(c) The time limits of this statute of limitations may be extended by agreement of the parties.

PART 17—ENFORCEMENT OF NON-DISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES CONDUCTED BY THE DEPARTMENT OF THE TREAS-URY

Sec.

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AUTHORITY: 29 U.S.C. 794.

Source: $56\ FR\ 40788$, Aug. 16, 1991, unless otherwise noted.

§17.101 Purpose.

The purpose of this part is to effectuate section 119 of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, which amended section 504 of the Rehabilitation Act of 1973 ("section 504") to prohibit discrimination on the basis of handicap in programs or activities conducted by Executive agencies or the United States Postal Service.

§17.102 Application.

This part applies to all programs or activities conducted by the agency, except for programs or activities conducted outside the United States that do not involve individuals with handicaps in the United States.